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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,683	01/20/2004	Thomas E. Broome	1001.1720101	5270

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EXAMINER	
SEVERSON, RYAN J	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/762,683	BROOME ET AL.	
	Examiner	Art Unit	
	Ryan Severson	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/04, 12/04, 06/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 12/08/2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Specification

2. The disclosure is objected to because of the following informalities: On page 8, line 2 of the specification, applicant states "... braided layer 24 22 ..." whereas the "braided layer" had previously been described using reference numeral 24, and reference numeral 22 referred to the "distal end of the proximal segment."

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 1, and 3-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Daniel et al. (6,171,327).** Daniel et al. reference discloses the invention substantially as claimed, including: an elongate tubular member (see Figure 22) having a "proximal segment" (251), a "distal segment" (252), and an "inner lumen" (253)

disposed therethrough; and a "dilator tip" (278) insertable in the distal segment. The distal segment is capable of radially expanding at least slightly when an axial force is applied (for example, when the tip is forced into the distal segment). The distal segment of the elongate tubular member shown in figure 22 is also interpreted to include the tapered portion on the left-hand-side of the drawing that connects to the proximal segment of smaller diameter.

Regarding claim 3, the tapered portion of the distal segment of Daniel et al. reference could be formed of a braid, as shown in figures 3 and 4. The braid between the proximal and distal portions of the elongate tubular member serves to increase flexibility and aid in the lengthening and shortening of the elongate tubular member (see column 5, lines 57-67 and column 6, lines 1-6).

Regarding claim 4, the dilator tip has a generally circular cross section, as it is inserted into the distal end of a tubular member, and therefore must be circular in cross section.

Regarding claims 5-7, the tip has a "proximal section" (the portion of the tip 278 which is inside the distal end of the tubular member in figure 22), a "distal section" (the portion outside the distal end of the tubular member in figure 22), and an "inner lumen" disposed therethrough, as shown in figure 22. Figure 22 also shows the dilator tip fitted tightly in the distal segment. The distal section of the tip is distally tapered (280).

Regarding claims 8 and 9, the elongated tubular member is capable of slightly expanding radially to encompass an embolic protection filter (21).

Regarding claims 10 and 11, the elongated tubular member of Daniel et al. reference can be configured either for use over-the-wire or for single operator exchange (see Column 5, Lines 43-47).

4. **Claims 12 and 14-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Daniel et al. (6,171,327).** Daniel et al. reference discloses the invention substantially as claimed, including: an elongate tubular member (see Figure 22) having a "proximal segment" (251), a "distal segment" (252), and an "inner lumen" (253) disposed therethrough; and a "dilator tip" (278) insertable in the distal segment. The distal segment is capable of radially expanding at least slightly when an axial force is applied (for example, when the tip is forced into the distal segment). The distal segment of the elongate tubular member shown in figure 22 is also interpreted to include the tapered portion on the left-hand-side of the drawing that connects to the proximal segment of smaller diameter. The tapered portion of the distal segment of Daniel et al. reference could be formed of a braid, as shown in figures 3 and 4. The braid between the proximal and distal portions of the elongate tubular member serves to increase flexibility and aid in the lengthening and shortening of the elongate tubular member (see column 5, lines 57-67 and column 6, lines 1-6).

Regarding claim 14, the dilator tip has a generally circular cross section, as it is inserted into the distal end of a tubular member, and therefore must be circular in cross section.

Regarding claims 15-17, the tip has a "proximal section" (the portion of the tip 278 which is inside the distal end of the tubular member in figure 22), a "distal section"

(the portion outside the distal end of the tubular member in figure 22), and an "inner lumen" disposed therethrough, as shown in figure 22. Figure 22 also shows the dilator tip fitted tightly in the distal segment. The distal section of the tip is distally tapered (280).

Regarding claims 18 and 19, the elongated tubular member is capable of slightly expanding radially to encompass an embolic protection filter (21).

Regarding claims 20 and 21, the elongated tubular member of Daniel et al. reference can be configured either for use over-the-wire or for single operator exchange (see Column 5, Lines 43-47).

5. **Claims 22 and 24-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Daniel et al. (6,171,327).** Daniel et al. reference discloses the invention substantially as claimed, including: an elongate tubular member (see Figure 22) having a "proximal segment" (251), a "distal segment" (252), and an "inner lumen" (253) disposed therethrough; and a "dilator tip" (278) insertable in the distal segment. The distal segment is capable of radially expanding at least slightly when an axial force is applied (for example, when the tip is forced into the distal segment). The distal segment of the elongate tubular member shown in figure 22 is also interpreted to include the tapered portion on the left-hand-side of the drawing that connects to the proximal segment of smaller diameter. The tip has a "proximal section" (the portion of the tip 278 which is inside the distal end of the tubular member in figure 22), a "distal section" (the portion outside the distal end of the tubular member in figure 22), and an "inner lumen"

disposed therethrough, as shown in figure 22. Figure 22 also shows the dilator tip fitted tightly in the distal segment.

Regarding claim 24, the tapered portion of the distal segment of Daniel et al. reference could be formed of a braid, as shown in figures 3 and 4. The braid between the proximal and distal portions of the elongate tubular member serves to increase flexibility and aid in the lengthening and shortening of the elongate tubular member (see column 5, lines 57-67 and column 6, lines 1-6).

Regarding claim 25, the dilator tip has a generally circular cross section, as it is inserted into the distal end of a tubular member, and therefore must be circular in cross section.

Regarding claim 26, the distal section of the tip is distally tapered (280).

Regarding claims 27 and 28, the elongated tubular member is capable of slightly expanding radially to encompass an embolic protection filter (21).

Regarding claims 29 and 30, the elongated tubular member of Daniel et al. reference can be configured either for use over-the-wire or for single operator exchange (see Column 5, Lines 43-47).

6. **Claim 31 is rejected under 35 U.S.C. 102(b) as being anticipated by Daniel et al. (6,171,327).** Daniel et al. reference discloses the invention substantially as claimed, including: an elongate tubular member (see Figure 22) having a "proximal segment" (251), a "distal segment" (252), and an "inner lumen" (253) disposed therethrough; and a "dilator tip" (278) insertable in the distal segment. The distal segment is capable of radially expanding at least slightly when an axial force is applied

(for example, when the tip is forced into the distal segment). The distal segment of the elongate tubular member shown in figure 22 is also interpreted to include the tapered portion on the left-hand-side of the drawing that connects to the proximal segment of smaller diameter. Daniel et al. reference also discloses an "embolic protection filter" (21) disposed about an "elongated wire" (26). The dilator tip (278) engages a "stop" (29) disposed about the elongated wire (see Figure 22).

7. **Claim 32 is rejected under 35 U.S.C. 102(b) as being anticipated by Daniel et al. (6,171,327).** Daniel et al. reference discloses the invention substantially as claimed, including: an elongate tubular member (see Figure 22) having a "proximal segment" (251), a "distal segment" (252), and an "inner lumen" (253) disposed therethrough; and a "dilator tip" (278) insertable in the distal segment. The distal segment is capable of radially expanding at least slightly when an axial force is applied (for example, when the tip is forced into the distal segment). The distal segment of the elongate tubular member shown in figure 22 is also interpreted to include the tapered portion on the left-hand-side of the drawing that connects to the proximal segment of smaller diameter. Daniel et al. reference also discloses an "embolic protection filter" (21) disposed about an "elongated wire" (26). The tip has a "proximal section" (the portion of the tip 278 which is inside the distal end of the tubular member in figure 22), a "distal section" (the portion outside the distal end of the tubular member in figure 22), and an "inner lumen" disposed therethrough to slidably receive the elongated wire, as shown in figure 22. Figure 22 also shows the dilator tip fitted tightly in the distal

segment. The distal section of the dilator tip (278) engages a "stop" (29) disposed about the elongated wire (see Figure 22).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. **Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Daniel et al. (6,171,327) as applied to claim 1 above, and further in view of Nilsson (5,873,851).** Daniel et al. reference discloses the invention substantially as claimed, including: an elongate tubular member having a "proximal segment" (251), a "distal segment" (252), and an "inner lumen" (253); and a "dilator tip" (278) insertable in the distal segment. However, Daniel et al. reference does not disclose varying the thickness of the proximal segment along its length. Attention is drawn to Nilsson reference, which teaches the wall thickness of an outer cannula (tubular member) can have varying wall thickness (see Column 5, Lines 9-19) to provide a more flexible and

resilient central section to assist in navigation through tortuous lumens. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to vary the wall thickness of the proximal segment of Daniel et al. reference along its length to provide a more flexible and resilient central section to assist in navigation through tortuous lumens.

9. **Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Daniel et al. (6,171,327) as applied to claim 12 above, and further in view of Nilsson (5,873,851).** Daniel et al. reference discloses the invention substantially as claimed, including: an elongate tubular member (see Figure 22) having a "proximal segment" (251), a "distal segment" (252), and an "inner lumen" (253); and a "dilator tip" (278) insertable in the distal segment. The tapered portion of the distal segment of Daniel et al. reference could be formed of a braid, as shown in figures 3 and 4. However, Daniel et al. reference does not disclose varying the thickness of the proximal segment along its length. Attention is drawn to Nilsson reference, which teaches the wall thickness of an outer cannula (tubular member) can have varying wall thickness (see Column 5, Lines 9-19) to provide a more flexible and resilient central section to assist in navigation through tortuous lumens. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to vary the wall thickness of the proximal segment of Daniel et al. reference along its length to provide a more flexible and resilient central section to assist in navigation through tortuous lumens.

10. **Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Daniel et al. (6,171,327) as applied to claim 22 above, and further in view of Nilsson (5,873,851).** Daniel et al. reference discloses the invention substantially as claimed, including: an elongate tubular member (see Figure 22) having a "proximal segment" (251), a "distal segment" (252), and an "inner lumen" (253); and a "dilator tip" (278) insertable in the distal segment. The tip has a "proximal section" (the portion of the tip 278 which is inside the distal end of the tubular member in figure 22), a "distal section" (the portion outside the distal end of the tubular member in figure 22), and an "inner lumen" disposed therethrough, as shown in figure 22. Figure 22 also shows the dilator tip fitted tightly in the distal segment. However, Daniel et al. reference does not disclose varying the thickness of the proximal segment along its length. Attention is drawn to Nilsson reference, which teaches the wall thickness of an outer cannula (tubular member) can have varying wall thickness (see Column 5, Lines 9-19) to provide a more flexible and resilient central section to assist in navigation through tortuous lumens. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to vary the wall thickness of the proximal segment of Daniel et al. reference along its length to provide a more flexible and resilient central section to assist in navigation through tortuous lumens.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. 6,447,530 to Ostrovsky et al., 5,300,086 to Gory et al., 5,649,953 to Lefebvre, and 6,468,291 to Bates et al.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan Severson whose telephone number is (571) 272-3142. The examiner can normally be reached on Monday - Friday 8:00 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ryan Severson
October 11, 2006

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SUPERVISORY PATENT EXAMINER
10/15/06